clinical trials. We aim to propose policy recommendations for increasing use of real-world evidence (RWE) that increases safety and efficacy information for patients with multimorbidities. METHODS/STUDY POPULATION: Conduct a systematic policy analysis on the current regulatory landscape of RWE, referencing the 2020 FDA Guidance "Enhancing the Diversity of Clinical Trial Populations." Evaluate guidelines using the Department of Health and Human Services' (HHS) 2016 Regulatory Impact Assessment (RIA) Framework. Utilize the Center for Drug Evaluation and Research's New Molecular Entity Database to identify novel hypertensive drugs approved after 2006, and assess clinical studies' alignment with the 2020 Guidance. Review additional policies, FDA guidelines, and ICH documents to establish baseline compliance. Two case studies will evaluate past policy impacts on drug development. Assess costs and benefits of increasing multimorbid patient enrollment to inform a policy framework. RESULTS/ANTICIPATED RESULTS: Anticipated results include all components of the HHS's RIA and a policy framework informed by the assessment. To identify problems, an analysis of clinical trial exclusion criteria in novel hypertensive drugs will be conducted to show diversity and enrollment gaps in regulatory policy, referencing the FDA's 2020 Guidance. The RIA's cost–benefit analysis will highlight costs faced for utilizing RWE and expanding enrollment criteria in Phase III studies. The cost–benefit analysis, RIA, and case studies will inform a policy framework that explains dynamics between stakeholders and outline policies that increase clinical trial representation in ways that are less burdensome to sponsors and patients. DISCUSSION/SIGNIFICANCE OF IMPACT: By understanding the barriers to enrolling participants with multimorbid conditions, we can outline incentives to increase diverse trial populations, helping healthcare providers choose more treatments for complex conditions. This research supports policy recommendations to make drugs more representative of conditions the population faces.

Team Science

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Team science training needs and preferences for clinical research professionals: A focus group analysis

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OBJECTIVES/GOALS: To present findings from a focus group study that evaluate clinical research professionals' (CRPs) team science learning preferences. The study aims to better understand CRPs' experiential perceptions of team science skills, training gaps, team cohesion, conflict, and contributions for their preferred team science training. METHODS/STUDY POPULATION: This study targeted CRPs across various roles in Academic Health Centers via focus groups. The focus groups will assess current skills, identify training gaps, and share experiences on team cohesion, team conflict, team contribution, and their thoughts and perceptions about clinical research professional team science training. The focus groups will be held via Zoom in the Autumn of 2024 with volunteer participants from an initial survey that was conducted earlier in 2024. We will report on combined data from multiple 90-minute focus groups, with approximately 6 participants per session. RESULTS/ANTICIPATED RESULTS: The focus group facilitator's guide includes questions informed by the CRP team science learning needs assessment results and other questions on team issues that would benefit from focused training. Focus group methods and demographic characteristics of the participants by role and experience level will also be presented. Qualitative analyses of recorded focus-group discussions will present key themes by demographic groups, and as a whole, these data will contribute to the development of CRP team science educational programs and toolkits. DISCUSSION/SIGNIFICANCE OF IMPACT: CRPs are vital members of clinical translational science teams. Overlooking CRP team science training can negatively affect the efficiency and effectiveness of the clinical translational science enterprise. CRP team science skills will foster a more collaborative and productive research environment.

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A CTS team approach to leveraging EHR data for predicting necrotizing enterocolitis in NICU

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OBJECTIVES/GOALS: This research aims to harness electronic health records (EHR) combined with machine learning (ML) to predict necrotizing enterocolitis (NEC) in preterm infants using data up to their first 14 days of life. We aim to provide interpretable results for clinical decisions that can reduce infant mortality rates and complications from NEC. METHODS/STUDY POPULATION: Through a retrospective cohort study using data from the University of Florida Integrated Data Repository and One Florida, we will develop machine learning models suitable for sequential data to predict NEC. Our inclusion criteria include very low birth weight (VLBW; < 1500g) infants born < 32 weeks gestation and EHR data availability from the first 14 days of life. We will include infants with NEC and infants without NEC to train our ML model. Exclusion criteria include infants diagnosed with spontaneous intestinal perforation and severe congenital anomalies/defects requiring surgery. RESULTS/ANTICIPATED RESULTS: We anticipate that our model will provide an accurate and dynamic prediction for the risk of NEC in neonates using data up to the first 14 days of life. Our model will be interpretable to identify key risk factors and can integrate real-world clinical insights to increase early detection and improve patient outcomes. DISCUSSION/SIGNIFICANCE OF IMPACT: The development of a model to predict NEC could be used in neonatal intensive care guidelines and protocols and could ultimately decrease mortality, reduce complications, improve the overall quality of care, and lower healthcare costs associated with NEC.

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